October 1, 1999

MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate Pesticide Temephos

FROM: Margaret Rice, Chemical Review Manager, SRRD
for the Temephos Reregistration Team
Office of Pesticide Programs

TO: OPP Public Docket for Temephos
Docket # 34147

Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (63 FR 48213, September 9, 1998) of preliminary risk assessments for the seven organophosphate chemicals: cadusafos, dimethoate, ethoprop, fenthion, sulfotepp, temephos and tribuphos. Part I of this document addresses comments specific to temephos, and Part II focuses on non-chemical-specific comments. By "non-chemical-specific" we mean that the comment was submitted to the OPP Public Dockets for each of the seven chemicals or for a significant sub-set of the seven. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the risk assessments.

Part I: Temephos Specific Comments and Responses

A. Response to Comments on the Health Effects Assessment

Temephos specific comments related to the preliminary health effects assessment were received only from the registrant, Clarke Mosquito Control Products, Inc. of Roselle, Illinois.

1. Comments from Clarke Mosquito Control Products, Inc.

The registrant's primary concern was the Agency's use of a default assumption of 100% dermal absorption for handler exposure scenarios. Subsequently they provided the Agency with a study from the open literature performed by the United States Army Environmental Hygiene Agency, entitled "Toxicological Assessment of ABATE® (0,0,0',0'-tetramethyl-0,0'-thio-di-p-phenylene phosphorothioate) Dermal Penetration of Radio-Labeled ABATE." In the study the dermal penetration of ABATE was measured in three animal species: rabbits, rats and dogs. Results indicated dermal absorption of over 50% in rabbits, 38% in rats and approximately 5% in dogs.

Response:

The Agency has reviewed the study submitted by Clarke and classified it as "acceptable-non-guideline." Although the study had many deficiencies, the Agency determined that the rat data were acceptable for risk assessment purposes. The preliminary worker risk assessments have been revised to reflect a dermal absorption value of 38%.

Of the 3 calculated values in the Army study, EPA has chosen to use the 38% dermal absorption demonstrated in the rat, because the rat is the required species for guideline dermal toxicity studies (Test Guidelines 870.7600). These guidelines have been designed and validated for the rat. The rat was not intended as a model of dermal absorption through human skin but rather as a test system for dermal absorption because the rat has been used extensively for metabolic and toxicological studies. In the temephos risk assessment, for example, the toxicological endpoint was chosen from a rat oral study. Therefore, it is most appropriate to adjust the oral NOAEL (no observable adverse effect level) in that study with a dermal absorption percentage derived from a study conducted with the same species.

2. Comments from Individuals

A private citizen, John Abbotts, submitted comments to all seven chemical dockets opened on September 9, 1998. Responses to Mr. Abbotts general comments are given in section II.B.1, below. The following of Mr. Abbotts comments relate specifically to temephos:

Comment: The Agency should act immediately to cancel all registrations for products, such as temephos, for which registrants are more than 5 years late in meeting reregistration data requirements.

Response: EPA issued a reregistration Data Call-In (DCI) for temephos on November 14, 1991. In response to the DCI, the registrant at that time, American Cyanamid, submitted a request for a low volume/minor use. EPA denied the waiver (November 17, 1993) and the denial was again rebutted by American Cyanamid (December 31, 1993). Since that time, the registration of technical temephos has been transferred to Clarke Mosquito Control Products, Inc., and the use

of temephos has dropped from approximately 100,000 lbs/ai/yr to approximately 20,000 to 40,000 lbs/ai/yr. The sole remaining use of temephos supported for reregistration is to control mosquito, midge, gnat, punkie and sandfly larvae.

EPA has not proceeded with cancellation of the remaining larvicidal use of temephos for several reasons. First, the Agency's own assessment, supported by comments from the US Department of Agriculture and the Department of Health and Human Services, indicate that temephos has an important role in Public Health both in the United States and elsewhere in the world. Temephos is low cost, fast acting and is considered the most reliable tool for controlling the larvae of mosquitos that transmit eastern equine encephalitis and dengue fever. None of the available alternative larvicide, such as *Bacillus thuringiensis israelensis,*methoprene, oils or pyrethrins, is an adequate stand-alone substitute for temephos. As one of the few remaining organophosphate larvicide, temephos is critical in resistance management programs.

Secondly, because of its short half-life and limited use pattern , primarily in salt water tidal areas, highly polluted temporary pools, tire piles and standing water, exposure to the general population including children, is limited.

Finally, because temephos has been used throughout the world by agencies such as the World Health Organization (WHO), there is much information on its toxicity, fate and effects available in the open literature. The registrant and some of the mosquito abatement districts that rely on temephos in their programs, have provided EPA with field monitoring data and literature studies targeted at the existing data gaps. While this information does not meet guideline requirements, it is sufficient to enable the Agency to conduct risk assessments for the limited remaining use.

Comment: The Agency should promptly revoke all obsolete tolerances for temephos.

Response: The Agency has revoked all tolerances for temephos. See the Federal Register (63 FR 5910) published on February 5, 1998 for the final temephos tolerance revocation.

B. Response to Comments on the Ecological Assessment

Comments on EPA's preliminary ecological assessment (October 13, 1998) were received from the registrant, Clarke Mosquito Control Products, Inc. and the Lee County Mosquito Control District. The Clarke submission consisted of "typical use scenarios" for both the liquid and the granular formulations of temephos, field data previously collected by American Cyanamid Co., and several studies from the open literature. Lee County's submission consisted of ecological impact assessments of salt water organisms and communities conducted by Mote Marine Laboratory over a period of several years. The impact assessments had been required by the State of Florida to permit the use of temephos on state-managed lands.

Together the two submissions were intended to address each of the 15 environmental fate and effects data gaps that had been identified in the preliminary assessment. EPA's complete review of this material can be found as ATTACHMENT 1 to this memorandum.

In general, EPA found that while the studies submitted were not conducted according to good laboratory practices (GLP) and thus did not satisfy guideline requirements, they contained much useful chemical-specific information that allowed an assessment of the ecological risks of temephos.

Part II: Non-Chemical-Specific Comments and Responses

Non-chemical-specific comments were received from: Idaho Farm Bureau Federation; National Cotton Council; Natural Resources Defense Council (NRDC); American Farm Bureau Federation; Fish and Wildlife Service, Division of Environmental Contaminants; Southern Professional Fruit Workers Conference (held at Clemson University); and 14 individuals, 13 of whom identified themselves as pest control operators (PCOs) or otherwise associated with the professional pest control industry. The other individual commentor, John Abbotts, provided no organizational affiliation.

Because there are several recurring issues in the comments that were submitted, we have chosen to divide our responses into two sub-sections. In order to avoid repetition, sub-section A deals with comments that are closely related and were repeated in more than one of the submissions, and with comments that are testimonial in nature. Sub-section B responds to those comments that are unique to each submission and refers the reader to the appropriate common responses in sub-section A.

A. EPA Responses to Recurring Issues in the Non-Chemical-Specific Comments

1. Comments Related to Common Mechanism of Toxicity

Comments: Several commentors, including the NRDC and Private Citizen Abbotts, questioned why EPA has not considered a common mechanism of toxicity in these OP risk assessments.

Response: EPA is required under FQPA to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate pesticides should be considered to operate via a common mechanism of toxicity, cholinesterase inhibition, unless and until the Agency receives data demonstrating otherwise.

In the Federal Register of August 6, 1998 (63 FR 42031), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides." The guidance document describes

the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. The 60-day comment period ended October 8, 1998. The revised guidance was issued in February, 1999. In developing this document, the Agency solicited advice from the FIFRA Scientific Advisory Panel (SAP) in February 1997; a year later (March 1998), OPP reported its progress to the SAP.

With respect to the comments that EPA has not considered common mechanism in these assessments, the Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed. Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, the International Life Sciences Institute (ILSI) is independently exploring appropriate methods and developing a framework for performing a cumulative risk assessment. ILSI held a workshop on this subject in September 1998, and recently submitted a report to the Agency outlining its findings. The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document. This guidance document is currently scheduled for late summer/early fall of 1999 with a 60-day comment period.

Until a method is available, EPA intends to complete risk assessments for individual OPs and proceed with the public process for development of risk mitigation strategies.

2. Comments Related to Additional Data and Default Assumptions

Comments: The American Farm Bureau Federation, The National Cotton Council and Private Citizen Abbotts encouraged EPA to obtain the data necessary to conduct realistic risk assessments. A common theme was that EPA should use actual data, particularly usage data, and avoid default assumptions in its assessments. Private Citizen Abbotts encouraged EPA to cancel all registrations, rather than make assumptions, when required data are missing.

Response: In phase four of reregistration, EPA exercised its data call-in authority to require studies to upgrade chemical databases to current scientific standards. Most of the OPs were subject to reregistration DCIs and registrants have been allowed ample time to submit those studies. EPA makes its reregistration and tolerance reassessment decisions on the best data that are available. Where data are incomplete EPA may compensate by using an additional uncertainty factor or making a reasonable health-protective assumption. This has long been EPA practice, and is reinforced by FQPA's emphasis on the importance of the use of an additional safety factor where data are incomplete.

It should be noted, however, that the OP risk assessments that were in the docket at the time this comment was submitted were “preliminary,” and that many of the first assessments were completed prior to receipt of all data. During the public comment and response period, EPA has continued its evaluations of available data, e.g., Monte Carlo analyses and other data, for these seven chemicals, and these evaluations have been incorporated into the refined risk assessments. In general, if additional, pertinent data are submitted prior to or during the comment periods, EPA will take these data into account in its revised assessments.

For a discussion of the sources of use and usage data and how EPA employs these data in its assessments, the reader is referred to a science policy paper entitled, "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management." An FR Notice announcing the availability of this paper for a 60-day public comment period was published July 14, 1999. The draft document is available on EPA's web page at: http://www.epa.gov/oppfead1/trac/science.

3. Comments Related to Application of the FQPA 10X Safety Factor

Comments: The NRDC commented that EPA failed to demonstrate the existence of reliable data for most OPs to justify departure from the use of the FQPA 10X safety factor. They also requested that EPA offer an explanation as to why the additional safety factor should not be retained for all OPs that are not supported by a developmental neurotoxicity study.

Response: OPP has developed criteria for retaining, reducing, and removing the additional ten-fold safety factor provided for in the FQPA to account for special susceptibility of infants and children to the effects of pesticide exposures. These criteria involve a weight-of-evidence consideration of both the nature and severity of effects observed in young animals, as well as the adequacy of the data base for the chemical. OPP's rationale for these criteria has been reviewed at various stages of development by the Scientific Advisory Panel (SAP). OPP has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor.

In addition, an Intra-Agency workgroup is looking at general considerations regarding the FQPA safety factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor.

The Agency’s policy for applying the FQPA 10-fold safety factor is currently one of the science policy issues available for public comment. Both the SOP and the Intra-Agency workgroup draft guidance document were discussed at the May, 1999, SAP meeting. An FR notice announcing the availability of these documents was published on July 8, 1999. The deadline for comments has been extended to October 7, 1999.

The question of what constitutes a reliable data base for making decisions related to the

FQPA safety factor is being thoroughly reviewed. Once that review process is completed, EPA may need to revisit its SOPs and decide how best to incorporate the revised procedures into its ongoing decision making process.

It should be noted the EPA has recently (September 10, 1999) issued a Data Call-In (DCI) notice for all OP pesticides with food uses to fill any existing data gaps for acute, subchronic and developmental neurotoxicity data. This first notice will be followed shortly by other similar DCIs for these same data for other classes of chemicals known to be neurotoxic.

4. Comments Related to Highly Exposed Populations

Comments: NRDC noted that EPA failed to consider the increased potential for pesticide exposure to "sentinel" populations, such as farm worker children.

Response: NRDC has petitioned the Agency to designate farm children as a major identifiable subgroup under the FQPA. The Agency is currently evaluating the scientific and legal issues raised in that petition. Specifically related to the preliminary risk assessment for the first OPs, EPA acknowledges that exposures to farm worker children were not evaluated separately, i.e., as a distinct population sub-group. However, based on the limited data currently available to characterize actual pesticide exposure to children of agricultural workers, such as a 1997 biomonitoring study by Loewenherz, Fenske and others (Environ. Health Perspect. 105:1344-1353), we believe that the exposure estimates developed by EPA using the Agency's Residential Exposure SOPs and other available information are reasonably inclusive of the exposures likely to be experienced by this sub-group.

EPA is concerned about the disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below.

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding exposure of children to pesticides. The studies are looking at major ways children can be exposed (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a

five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Finally, based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children in the agricultural setting.

5. Comments Related to Relying on Sound Science

Comments: The National Cotton Council, American Farm Bureau Federation and Private Citizen Abbotts all supported EPA's reliance on sound science to make regulatory decisions. The National Cotton Council encouraged the Agency to finalize the nine science policy issues identified during the Tolerance Reassessment Advisory Committee (TRAC) before making regulatory decisions.

Response: EPA is committed to the principles outlined by Vice President Gore to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. It is primarily for that reason that the TRAC was formed and the pilot process for increased public participation in pesticide decisions was developed. However, EPA must balance the goal of providing for greater transparency and participation in development of science policy with its mission to ensure the safety of the food supply and the health of consumers, especially children, workers, and the environment. In order to accomplish our mission through timely decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk mitigation options. It should also be noted that FQPA does establish a statutory deadline to complete the reassessment of existing tolerances by 2006, and the Agency is making every effort to comply with that deadline.

6. Comments Related to a Transparent Process

Comments: The National Cotton Council, American Farm Bureau Federation, Natural Resources Defense Council (NRDC) and Private Citizen Abbotts applauded EPA's efforts to make a transparent process for the reregistration of the organophosphate pesticides. NRDC felt that further efforts were needed to ensure that all risk assessment methods used to establish tolerances (e.g. Monte Carlo methods and underlying assumptions) were transparent. Private Citizen Abbotts noted that the formats for risk assessments were not always consistent, that the "bottom line" risk could not always be determined, and that a table summarizing risks for all OPs would help in making risk management decisions.

Response: EPA agrees that a transparent process is essential to public participation and sound decision making. The Tolerance Reassessment Advisory Committee (TRAC) was established to ensure that the process for the reregistration of the organophosphate pesticides was transparent and open to all. EPA intends to continue its dialogue with the various constituents throughout the reregistration process.

EPA acknowledges inconsistencies in the assessments for the first 16 OPs. In many cases, the assessments were begun many months ago and have not been constantly updated to reflect new formats. In the revised risk assessments, we have made an effort to ensure consistency in the assumptions and the levels of refinement that are applied, given the data for each chemical. In an attempt to make the risk assessments easier to understand and compare, EPA has prepared risk summary and overview documents for each OP. These risk overview documents have been prepared in a standard, logical format and are intended to assist the reader by identifying key features and findings of the risk assessments, highlighting any assumptions and refinements that have been used, and discussing ways of further refining the risk assessments.

7. Comments Related to Transitioning to Safer Alternatives

Comments: American Farm Bureau Federation expressed concern that EPA administer FQPA in a practical and realistic way by allowing sufficient transition time for users to adapt to new or alternative products and practices. In his comments, Private Citizen Abbotts advocated linking approval of safer chemicals with cancellation of corresponding “older, riskier alternatives.”

Response: EPA's Registration Division has established a priority plan intended to encourage and expedite the registration of reduced risk pesticides and, particularly, alternatives to the OPs. However, this priority plan is not "linked" to cancellation of specific "older, riskier, alternatives." To do so would likely slow down both processes. In some cases, there may already be preferable alternatives, and thus no need to wait for a new reduced risk registration. Conversely, when a safer chemical is registered, it may take several years of use on actual field crops before its ability to completely replace another chemical is known and recognized.

With regard to the American Farm Bureau's concern, EPA is working closely with USDA and grower groups in developing risk mitigation and transition strategies.

B. EPA's Response to Submitter - Specific Comments

1. Comments from Private Citizens

Comment: Private Citizen John Abbotts submitted a detailed 15-page letter outlining his views on the Agency's preliminary risk assessments and made several suggestions for process improvements. In addition to the comments addressed above, Mr. Abbotts indicated that some of the risks presented in the preliminary assessments were substantive enough to trigger immediate regulatory action by the EPA.

Private Citizen Abbotts also advocated that the EPA quickly process all deletions of particular uses requested by registrants. He particularly cited a letter where the registrant for dimethoate, Cheminova, requested cancellation of all dimethoate residential uses. Similarly, Mr. Abbotts requested that the EPA revoke all tolerances for which there are no registered uses.

Private Citizen Abbotts expressed concern that the EPA was allowing other pesticides, such as cadusafos, to remain on the market, even though the risk assessment used residues of ½ the Limit of Detection (LOD) and percent crop treated data rather than tolerance level residues and 100% crop treated. He felt that the risks were unacceptable using 100% crop treated and tolerance level residues. Mr. Abbotts also suggested that EPA establish import tolerances based on toxicological data so that consumption at tolerance level would result in acceptable dietary risk.

Private Citizen Abbotts also made several suggestions for implementing a risk-reduction strategy to begin reducing the cumulative risks posed by organophosphates. These suggestions included requiring each registrant to reduce the cumulative risk from all of their registered organophosphate products to acceptable levels, requiring registrants to work together to reduce the risk on each commodity to a level consistent with the commodity's proportion of the diet, or creating market-based incentives for reducing the risks to organophosphates.

In his letter, Mr. Abbotts also maintains that the Agency should examine cumulative occupational risk.

Response: EPA disagrees that the risks outlined in the assessments for these seven chemicals are significant enough to require immediate regulatory action. All of these assessments are preliminary in nature and thus the stated risks likely overestimate the actual risk posed by the use of the chemical. Before demanding risk mitigation measures that may adversely affect the safety of the U.S. food supply, EPA has a duty to ensure that the risk assessment is as refined, and thus realistic, as possible.

EPA agrees with Mr. Abbotts assertion that use deletions should be processed quickly. However, registrants frequently propose to delete uses to mitigate risks without actually submitting amendments to remove those uses from their labels. In addition, other registrants may

have registered products with the same uses and be unwilling to remove them from their labels. Unless all registrants of a particular chemical request to delete these uses from their labels, these uses will remain part of the risk assessment. Finally, the Agency is committed to vetting proposed deletions with the grower community and other members of the public before taking any regulatory action. The TRAC (Tolerance Reassessment Advisory Committee) has been specifically established to promote this kind of dialogue among the public, grower groups, industry and EPA.

FQPA establishes a statutory deadline to complete the reassessment of existing tolerances by 2006. The Agency is making every effort to comply with that deadline. As part of this goal, EPA has taken actions to revoke all tolerances for which there are no registered uses and that are not supported for import purposes. See 65 FR 5907 published February 5, 1998.

In a worst-case risk assessment, such as that referenced by Mr. Abbotts for cadusofos, EPA typically assumes tolerance level residues and 100% crop treated. These worst-case assessments are used for screening purposes only and are an attempt to conserve Agency resources. If further refinements are needed to characterize dietary exposure, EPA calculations may include percent-crop-treated data, averages of field trial data or other information. The refined exposure estimates are so designated because they are more likely to approximate the pesticide residues people will actually consume in their diets.

Often, a residue chemistry data set contains some samples that are reported as not bearing detectable or quantifiable residues, i.e., residues are less than the LOD. This is frequently the case for early season applications, long treatment-to-harvest intervals, and/or monitoring of the food supply closer to the point of consumption. Given the above information, the Agency has chosen to assign a residue value of ½ LOD (or ½ LOQ if an LOD has not been determined) to samples with no detectable residues if it is known or believed that these samples have been treated with a pesticide. This is believed to represent a minimal distortion of reality if only a small proportion (e.g., less than approximately 10-15%) of the data are below detectable limits. The use of ½ LOD for nondetectable samples is widely used in EPA risk assessments when the appropriate conditions are met, as in the cadusafos risk assessment. For further discussion, please see the draft science policy paper entitled, “Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments,” (dated 11/30/98).

EPA currently establishes import tolerances in a manner similar to that used to establish domestic tolerances. Translations of the labels used overseas and the foreign field trial data are evaluated. A number of field trials are required which must demonstrate the range of climate conditions and cultural practices. These variations can lead to a range of residue values, which can vary from non-detectable to large concentrations. Using data from the field trials, EPA performs its risk assessment, refining residue estimates as necessary. If the risk is acceptable, EPA establishes a tolerance at a level that is higher than the highest residue value obtained in the field trial data as it does when establishing a tolerance for use of a pesticide domestically.

Mr. Abbotts is suggesting that import tolerances be set by a process in which the toxicity data are combined with the consumption data to generate the highest allowable pesticide concentration in the commodity. However, such a process would provide no assurances to farmers applying pesticides to their crops at the labeled application rates that the resulting produce would contain residues below the established tolerance levels at the farmgate where these levels are monitored for enforcement purposes. EPA must ensure that use at the labeled application rate will not result in produce containing residues that are greater than the tolerance level. Field trial data are needed to ensure that the produce grown will indeed contain residues at levels below the established tolerance. Currently the USDA's Pesticide Data Program (PDP) monitoring data is the best indication of actual pesticide residue levels at or near the point of consumption.

The Agency appreciates Private Citizen Abbotts proposals for risk mitigation strategies and, in fact, has initiated preliminary discussions about particular risk mitigation strategies that may cut across pesticides or commodities. The Agency expects that these discussions will likely address the value of particular pesticide uses irrespective of the identity of the registrant.

EPA recognizes that farmworkers may be exposed to multiple chemicals, however, as Mr. Abbotts mentions, occupational risk is not included in the FQPA statutory requirements for cumulative assessments. Currently EPA does not have a methodology for conducting such assessments and must continue to assess occupational risk based on a single chemical. Once the Agency establishes a method for determining cumulative exposure, it may be able to expand its guidelines to include occupational exposure scenarios.

See also responses to II.A.1, II.A.2, II.A.5, II.A.6 and II.A.7 above.

Comment: Thirteen individuals, who identified themselves as pest control operators requested that EPA: base its decisions on actual pesticide use, obtain necessary information through data call-ins, establish and communicate uniform policies to guide consistent implementation of FQPA, refrain from taking regulatory action based on unrealistic default assumptions.

Response: See responses to II.A2, II.A.5 and II.A.6 above.
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2. Comments from Universities and Extension Services

Comment: The Southeastern Professional Fruit Workers Conference, the annual meeting of applied fruit scientists (held at Clemson University in October, 1998) provided their evaluation of the OPs (and other pesticides) that are crucial in resistance management and IPM programs for crops in their area. The group identifies opportunities for mitigation (primarily reductions in numbers of applications and increased PHIs).

Response: This comment was submitted in response to the second group of seven OPs. However, because it pertains to some of the first nine, it was addressed it the response to comment document for the first nine OPs.

The information provided by the Fruit Workers Conference has been provided to our Biological and Economic Analysis Division and to each of the Chemical Review Managers for the chemicals named in the analysis. This type of information is useful to the Agency in determining the feasibility of mitigation such as reduced frequency and timing of pesticide applications, and in considering risk trade-offs, where appropriate.

3. Comments from Growers, Commodity and Marketing Groups

Comment: The National Cotton Council is concerned that exposures from gin trash as a feed additive are grossly overestimated. No cotton uses should be canceled based solely on unacceptable risk resulting from gin byproducts using current EPA assumptions. (Note: OPs with cotton uses include azinphos-methyl, methyl parathion, phorate, profenofos, naled, dicrotophos, and tribufos) The Council is working with the Agency to "adjust" these assumptions and indicated that they would be submitting additional data.

Response: EPA representatives met October 13, 1998, with a delegation from National Cotton Council (NCC) in response to their request to discuss cotton gin byproducts (CGB) and its proportion in livestock feeds. In addition to members of the NCC, representatives of cotton ginners associations (Texas Cotton Ginners Association, Southeastern Cotton Ginners Association, and the California Cotton Ginners Association) were present. These experts are familiar with CGB, its volume of production in the USA, and its use as animal feed.

EPA discussed how a risk assessment is performed, i.e., how CGB are factored into the beef and dairy cattle diets and how potential transfer of residues to meat and milk could therefore affect a person's daily dietary intake of pesticide residues. Table 1 of OPPTS Test Guidelines Series 860 currently lists CGB as a raw agricultural commodity comprising up to 20% of the diet of beef and dairy cattle.

Representatives of the ginners associations agreed that in some parts of the country CGB are fed at up to 10% of the diet to beef cattle when the cattle first enter the feed lot. CGB are then reduced to approximately 3% in the finishing rations. Based on this information, the NCC has asked EPA to reconsider how CGB are currently listed in Table 1.

EPA asked the NCC to provide detailed information concerning the disposition and use of CGB. Information submitted should be able to be independently verified by OPP. The NCC submitted a protocol for obtaining such information. EPA has approved the protocol and is currently awaiting submission of this information.

See also responses to II.A.2, II.A.5, and II.A.6 above.

4. Comments from Environmental and Consumer Groups

Comment: The Natural Resources Defense Council (NRDC) submitted a copy of their report, "Trouble on the Farm," and provided comments on four broad issues: 1) EPA fails to demonstrate the existence of reliable data for most OPs to justify departure from the use of FQPA 10X safety factor; 2) Preliminary assessments do not provide reasonable certainty of no harm, e.g. EPA did not consider "sentinel" population of farm worker children; 3) EPA must conduct a cumulative assessment; and 4) Often, e.g. azinphos-methyl, occupational risks are unacceptable even with maximum mitigation. These should be eliminated expeditiously

In addition, the NRDC urged EPA to account for "enantiomer" and metabolite toxicity in reassessing tolerances for the OPs. Enantiomers are mirror image molecules produced in the manufacture of organophosphate active ingredients. Specifically, the commentor raises concern over the possibility that specific enantiomers of these substances could be produced during manufacture, and that these enantiomers may be more toxic than other enantiomers that may be present. Hence, the risks posed by these substances could be greater than the risks anticipated by EPA's assessments.

Response: With respect to worker risks, EPA intends to complete risk assessments for individual OPs, taking into account any comments received during the public comment period. For the seven OPs, the public comment period closed on the risk assessments in November, 1998. According to the plan developed by the TRAC, EPA will respond to comments on the risk assessments and work with USDA and stakeholders to develop risk management options for risks of concern, including workers.

Regarding enantiomer toxicity, this issue was also raised in the comments and responses for the first nine OPs. Enantiomers of a given substance are isomers whose mirror images are not superimposable. Enantiomers have identical physicochemical properties, except in the direction in which they rotate a plane of polarized light. The Agency agrees with NRDC's comment that enantiomers of a given substance may vary in toxicity and, therewith, pose different risks to human health or the environment. In a given manufacturing process it is possible that more than one specific enantiomer can form, unless the reaction conditions and feedstocks are such that formation of only one enantiomer is possible. It is also possible that one enantiomer may be produced more readily than another enantiomer, and may predominate in the technical product. Even if an enantiomer is formed in low concentration relative to another enantiomer during synthesis of a technical product, it may still contribute significantly to the overall risk of the product if its toxicity is greater than the toxicity of the other enantiomer. Technical products of pesticide substances that can exist as two or more enantiomers usually do not undergo purification procedures that remove a specific enantiomer. These pesticide substances are generally used as obtained from synthesis, and are often comprised of more than one enantiomer.

Individual enantiomers of a substance may interconvert in plants, mammals or the environment. Hence, a specific enantiomer of a substance may be converted into its other enantiomer as a result of plant or animal metabolism, or release into the environment. It is also possible for a substance that cannot exist in enantiomeric forms (i.e., is achiral) to be metabolized to other substances for which enantiomers are possible and are formed.

The Agency also agrees with NRDC's comment that metabolites (e.g., plant, farm animal, or mammalian metabolites) of a pesticide substance are often sufficiently toxic so as to contribute to the overall risks associated with use of the pesticide and consumption of foods that contain the pesticide and its residues. In some instances a metabolite may have substantially greater toxicity than its parent substance.

EPA believes, however, that its risk assessments of the seven subject organophosphorus pesticides adequately take into account the toxicity of any of their enantiomers or metabolites. In assessing the risks posed by a given pesticide substance, EPA evaluates a number of factors that may contribute to risk. These include, for example: the mammalian toxicity of the parent substance; its mammalian metabolism from different routes of exposure; its metabolism in plants and livestock (e.g., dairy cows, steer, poultry); the known or potential toxicity of mammalian, plant and livestock metabolites; the environmental fate and ecotoxicity of the parent substance; dietary exposure to the parent substance and its plant and livestock metabolites; exposure that may result from consumption of waters that contain the pesticide or environmental degradates thereof; and exposure that may result from residential or occupational use of the pesticide. Plant and livestock metabolites of toxicological concern are identified by EPA from an evaluation of plant and animal metabolism studies required for registration or reregistration.

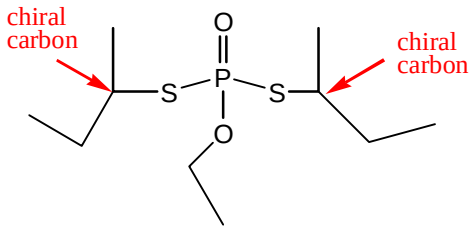
EPA also routinely evaluates the manufacturing processes used to synthesize pesticide active ingredients as part of its process to evaluate the risks posed by pesticides. Submission of information pertaining to method of manufacture is required for registration and reregistration of pesticides. The primary purpose of evaluating a manufacturing process of a given pesticide is to ascertain the composition of the technical product with regard to overall risk to human health and the environment. The evaluation includes an analysis and consideration of: the feedstocks, reagents, catalysts, solvents and any other substances used in the process; reaction conditions; pesticide yield; byproducts, and any other substances that are known, or could reasonably be anticipated to form under the reaction conditions of the process. EPA considers any impurities in the reactants or other substances used in the synthesis that may contaminate the technical product and contribute to overall risk. Once a method of manufacture has been reviewed and deemed acceptable by EPA, the registrant must use that method of manufacture. The registrant cannot change or modify a method of manufacture until the Agency has evaluated the method and its impact on overall risk of the pesticide technical product. Thus, the composition of a pesticide technical product as manufactured from a process deemed acceptable by EPA should remain consistent among different lots.

As stated above, technical products of pesticide substances that exist as two or more

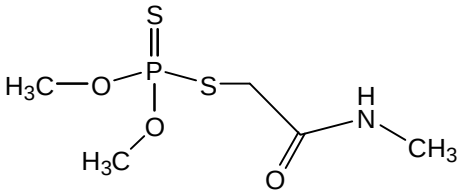
enantiomers often do not undergo purification procedures that remove a specific enantiomer, and these pesticide substances are generally used as obtained from synthesis. Current guidelines do not require that registrants provide EPA with information regarding which particular enantiomers are present, or their relative concentrations. EPA is generally unaware of which specific enantiomers or concentrations thereof are present in pesticide technical products. However, the presence and concentrations of specific enantiomers comprising a technical product are not expected to vary among manufactured lots because the same method of manufacture is used for each lot. While the Agency may not be aware of the presence or concentrations of specific enantiomers comprising the technical product of a pesticide substance for which enantiomers are possible, mammalian toxicity data required for registration (or reregistration) of the technical product represent the combined toxicity of the pesticide (including any enantiomers that are present) and its mammalian metabolites.

Environmental fate laboratory studies involving a pesticide substance are typically conducted using radio labeled substance in which the substance is radio labeled in at least at one site of the molecule. The Agency recognizes, however, that a specific enantiomer of a substance could convert to another enantiomer under actual environmental conditions. Environmental photolysis, for example, may lead to interconversion of one enantiomer to another. EPA evaluates geometrical, configurational and/or conformational isomer interconversions that occur in the environment, but only for those chemicals known to show specific isomer bioactivity. That is, one or more of the isomers are the only ones associated with pesticidal activity over the other isomers.

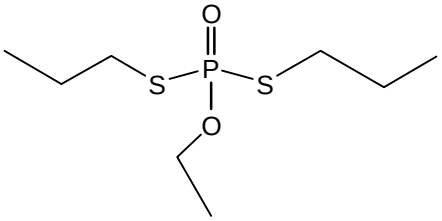
The structures of the seven subject organophosphorus substances are shown below:



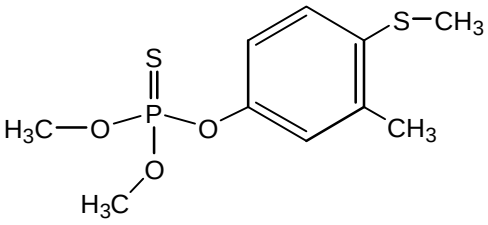
cadusafos



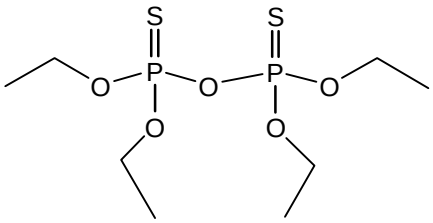
dimethoate



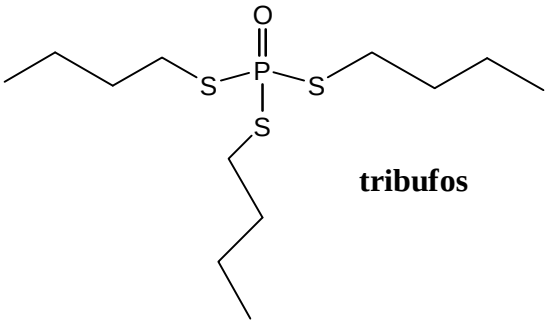
ethoprop



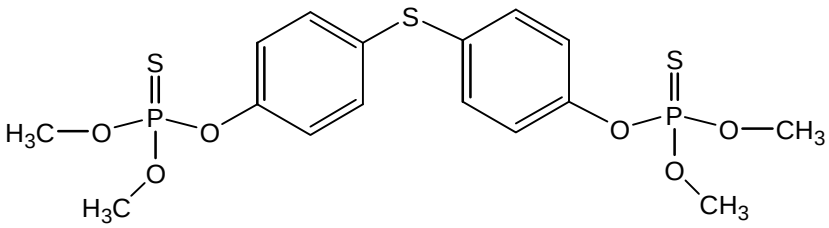
fenthion



sulfotep



tribufos



temephos

Of these seven substances only cadusafos can exist in enantiomeric forms. This substance has two chiral carbon atoms (as indicated) and, thus, a total of four distinct enantiomers are possible. The other six substances do not contain any atoms that are chiral and, therefore, it is not possible for them to exist as enantiomers. It is theoretically possible, however, that any of the seven substances could be metabolized in plants or mammals or degraded in the environment to other substances that could exist as enantiomers. Hydrolysis of one of the S-P bonds in ethoprop, for example, would result in a substance that has a chiral phosphorus atom and could exist as two distinct enantiomers.

The Agency does not know the relative ratios of the specific enantiomers in the technical product of cadusafos. However, the mammalian toxicity studies submitted by the registrant correspond to the technical product as manufactured and reflect the actual toxicity of the technical product and its metabolites. The same is also true for the cadusafos ecotoxicity studies submitted to the Agency. Therefore, even if one (or more) of the four enantiomers of cadusafos is (are) substantially more toxic than the other enantiomers, and is present in the technical product, its toxicity is expressed in the mammalian and ecotoxicity data submitted to the Agency and used in risk assessment of the technical product. The Agency does not expect differences in the composition of technical cadusafos among lots because the method of manufacture is (or will be) the same for each lot.

The environmental fate studies submitted for cadusafos were not intended to follow the fate of its individual enantiomers, or monitor for enantiomeric interconversions. Hence, EPA does not know to what extent, if at all, if the individual enantiomers of cadusafos interconvert in the environment. However, ecotoxicity data collected under current OPPTS test guidelines represent the ecotoxicity of the technical product (including any of its enantiomers that may be present), and its environmental degradates.

As previously stated, dimethoate, ethoprop, fenthion, sulfotepp, tribufos, and temephos do not contain any chiral atoms. These substances cannot exist in isomeric forms that are enantiomeric. Thus, the possibility of specific enantiomers having greater toxicity than other enantiomers, or that one enantiomer may be interconverted to another in the environment do not apply to these substances. While it is possible that any of these substance can be metabolized to substances that contribute to the toxicity of the parent substance, the mammalian toxicity data submitted for each of these substances and used for risk assessment purposes represent the combined toxicity of the parent substance and metabolites thereof. Also, any plant or livestock metabolites of toxicological concern have been identified by EPA and included in the risk assessments.

See also responses to II.A.1, II.A.3, II.A.4 and II.A.5 above.

5. EPA's Response to Comments from Other Federal Agencies

Comment: The Fish and Wildlife Service, Division of Environmental Contaminants, pointed out that four of the seven OPs have Final Biological Opinions (1989) for Endangered Species. In addition, FWS and EPA are currently in consultation on fenthion. FWS recommends that EPA implement, at a minimum, via label modifications and county bulletins, the applicable Reasonable and Prudent Alternative measures identified in 1989 Biological Opinions. EPA should also implement the risk reduction and mitigative measures identified in the OP ecological risk assessment documents to reduce hazards to non-target organisms.

Response: EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has included the pesticide use provisions from the 1989 Biological Opinion (as well as other opinions) or equivalent protective measures in the over 300 bulletins that have been completed and distributed.

The mitigation measures suggested in the preliminary ecological risk assessments, along with other measures that may be put forward during the comment period, will be considered in developing risk management options for these seven OPs. During Phase 5 of the TRAC process for each of these chemicals, the public is invited to provide comment on risk management options.

ATTACHMENT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 5, 1999

MEMORANDUM

SUBJECT: Response to Public Comments on Ecological Risk Assessment for Temephos (Chem. Code 059001; DP Barcode D253700 and D 254124).

TO: Kathy Monk, Chief
Reregistration Branch II
Special Review and Reregistration Division (7508-W)

Margaret Rice, PM team Reviewer
Reregistration Branch II
Special Review and Reregistration Division (7508-W)

FROM: James J. Goodyear, Biologist
William Evans, Biologist
Ronald Parker, Senior Environmental Engineer
Silvia C. Termes, Chemist
Temephos Team
Environmental Fate and Effects Division 7507C

THRU: Tom Bailey, Chief
Ecological Hazard Branch

Betsy Behl, Chief
Fate and Monitoring Branch
Environmental Fate & Effects Division 7507C

In response to public comments received February 17, 1999 concerning the EFED science chapter, we have outlined below our evaluation of data submitted by the Registrant and Lee County (Florida) Mosquito Control District to address guideline data requirements. Most of the

data submitted was from non-guideline field studies and do not satisfy the data requirements under CFR 40, Part 158. Nevertheless, information from some of these studies was useful as supplemental data in the EFED RED science chapter.

Comments from Clarke Mosquito Control Products, Inc.

A statement in the Clarke's rebuttal suggested that further testing of reproductive effects in waterfowl would be unnecessary. As discussed in EFED's revised risk assessment (RED chapter) an acceptable study has not been submitted, however field data reflecting actual use that have been submitted for review indicate that there is little impact on birds. Therefore, EFED will not require a chronic bird study at this time. However, it should be noted that current label allows treatments "as necessary" with no limitations on intervals between applications or maximum number of applications per season. Because of the potential for continuous exposure, labels should be modified to reflect more accurately the actual use conditions. For example, limitations could be set on the frequency of applications, the application rates, intervals between applications, and/or the maximum yearly poundage, unless specific conditions warrant exceptions.

Clarke also states that at the EECs resulting from maximum application rates in 12 inches of water are 0.18 ppm and 0.017 ppm for granular and liquid applications, respectively. The basis on which these calculations are determined is not explained. Further, in the EFED modeled scenario for a 12 inch (30 cm) body of water receiving two applications at a 90-day interval was 0.024 ppm. In addition, the statement claiming that temephos bonds to organic matter and is, therefore, unavailable to nesting waterfowl is unsubstantiated. And finally, the public position that dermal absorption from direct exposure to granules will be insignificant is not supported by any data.

Clarke indicated concern over EFED’s use of the rainbow trout as an indicator species for aquatic toxicity, because it of the supposition that a very small percentage of mosquito breeding sites contain rainbow trout. They further postulate that on the occasion that fish are present, bluegill would be the more typical species. EFED routinely uses a warm water fish species (bluegill) and a cold water species (rainbow trout) to represent all species of fish in North America. Furthermore, these two fish species are tested to estimate the general sensitivity of fish in general, not toxicity specific to any one species or habitat per se. In fact, there may be any number of fish species inhabiting treated waters which have greater sensitivity to temephos than rainbow trout or bluegill. Additionally, no laboratory toxicity tests with marine/estuarine (sheepshead minnow) fish has been provided. A fish toxicity test with a marine/estuarine species is required because temephos is directly applied to marine/estuarine environments.

Review and evaluation of field studies submitted by the Registrant and Lee County Florida Mosquito Control District are presented below. These studies were submitted in lieu of standardized laboratory tests to address CFR 40, Part 158 guideline tests.

Data Submitted by Clarke

Exhibit 1, *"Abate: Effects of the Organophosphate Insecticide on Bluegills and Invertebrates in Ponds"*[1] was submitted in support of waiving the Fish Early Life-stage and Fish Life-cycle studies. This study was conducted at the Columbia National Fisheries Research Laboratory (Columbia, Missouri) to determine if bluegill and aquatic invertebrates were adversely affected by three applications of Abate at 40 and 4 μg ai/L applied at monthly intervals. Six 0.04 ha earthen ponds were used in this study, with an average depth and volume of 0.88 m and 311 m^3, respectively. The results indicated that fewer bluegill fry were produced in treated ponds and that acetylcholinesterase activity was not affected at the 4 μg ai/L rate. In addition, growth was significantly greater for both fry and adults presumably due to heavy feeding on dead or moribund Diptera larvae affected by the Abate applications. The higher application rate of 40 μg ai/L caused lower total numbers of fry and reduced the numbers of fry per female. In addition, acetylcholinesterase activity was strongly inhibited after the second and third applications.

It was further recommended by the study authors that Abate not be applied at the higher rate to waters containing fish when water temperatures exceeded 20°C. It is of interest to note that the EFED aquatic exposure model estimated concentrations (EECs) in water greater than 40 μg ai/L after only 2 applications at the 0.5 lb ai/A rate using a 90 day interval between applications. These results offer some support for limiting the frequency of applications.

This study cannot substitute Fish Early Life-Stage (72-4-a) and Fish Life-Cycle (72-5) studies. The most important reason is that measured concentrations of the test substance were not maintained throughout the test. Indeed, concentrations were below 1.0 μg ai/L after one day and below the limits of detection (0.3 μg/L) 8 days after the second application. As such, a reliable NOAEC was not obtained. In addition, this study was not conducted under laboratory conditions as required by EPA protocols.

Exhibit 2, *"Effects of Abate (Temephos) on Non-Target Aquatic Organisms in a Natural Pond Undergoing Mosquito control Treatment"*[2] was submitted to satisfy the requirements for the 72-4 guideline fish chronic studies. This study does not fulfil the guideline for a number of reasons, but mostly for the reasons stated below.

1. This study was designed and conducted as a general field study, not a chronic toxicity study. Instead of the guideline requirement of 56 days to obtain a reproductive endpoint NOAEC, this study was conducted for only 30 days.

2. Constant measured concentrations were not maintained throughout the experiment. The true fish exposure was not determinable.

Despite the inadequacies, the determined toxic endpoints merited use in the risk assessment. The study determined effects of temephos on non-target organisms under actual field conditions. One application of Abate EC (flowable) at 0.1 lb ai/A followed by a second application of the 1%

granular formulation using a 14-day interval between applications, did not result in acute fish mortality, growth effects or inhibition of acetylcholinesterase in fish brain. In laboratory toxicity tests, acute toxicity due to formulated product were shown to be 5 - 20 times greater than the active ingredient. For example, the LC_{50} for bluegill exposed to TGAI was 21.8 ppm , while the LC_{50} determined for Abate 4EC was 1.14 ppm. Likewise, For the rainbow trout, the LC_{50}s were 3.49 ppm and 0.16 ppm with TGAI and Abate 4EC, respectively.

Exhibits 3 and 4 were submitted as a response in support of waiving the Freshwater Invertebrate Life-cycle study (72-4(b)). **Exhibit 3** is titled *"Residues of CL 52,160 (temephos) in Water and Mud from Streams and Ponds"*[3] *and* ***Exhibit 4*** *is titled "Abate®: Abate and Abate Sulfoxide Residues in Environmental Samples - Water, Sediment and Four Aquatic Species."*[4] These studies were further submitted as evidence that temephos is not likely to be persistent in water due to its tendency to adsorb to organic material. The conclusion is that temephos is not bioavailable to organisms in the water.

Exhibit 3 was submitted as a 1 page summary with only the Scope and the Results section of the study attached. The details of this report are extremely sketchy and specific sites of streams and ponds in California and New Jersey nor the methods used were identified. In addition, the study as conducted in 1965, and methodology for testing residue samples may be much improved by today's standards. The study treated the sites with a single application rate of 1.0 lb CL 52,160/acre and ten applications 0.1 lb CL 52,160/acre at weekly intervals. (CL 52,160 is presumed to be the parent compound of temephos.) Samples of water and mud were taken from streams at the point of application and 500 and 1,500 feet downstream. Water samples were taken at the surface and at a 5-8 foot depths. The study concluded that residues in surface water were in the range of 100 - 300 ppb and dropped to less than 50 ppb in 24 hours. No detectable residues were found in the mud (limit of detection not stated). The fate of temephos was not discussed. This study, as presented, adds little to the risk assessment and does not support the waiving of the Freshwater Invertebrate Life-cycle study.

Exhibit 4 exposed four species of marine organisms to dosages of 0.5, 1.0, 3.0, 6.0, and 12 fluid ounces of ABATE® 4E to four species of marine organisms including Killifish, Grass shrimp, Blue Claw Crab, and American oyster under field conditions at Chrisfield, Maryland. Treatments were made 6/16, 6/30, and 7/28 followed by sampling 3 days after each treatment. In addition, a similar test was conducted at Newark, Delaware at 0.096 lb ABATE® 4E/acres in four applications. Water and sediment samples were taken 4 weeks after the final treatment and composite samples of killifish and shrimp were taken 7 days after the final treatment. The objective of the studies were to determine the effect of ABATE® on marine organisms in relation to the ecological food chain to satisfy part of the requirements on persistence of ABATE® in the environment.

No observations were made on lethal or sub-lethal effects of the test material, and hence neither a NOAEC nor a LC_{50} was obtained. Only residue levels were measured in the organisms and the water and sediment. This study, therefore, cannot substitute for the marine/estuarine data

requirements.

Although the study was conducted in 1971, residue samples showed the highest residue accumulation in oysters, however, the concentration is not given in the report. Crab residues ranged from 0.06 to 3.11 ppm after the second treatment. Sediment samples were measured at concentrations up to 0.53 ppm for the ABATE 4E, while the ABATE sulfoxide concentrations peaked at 0.40 ppm thirty minutes after the fifth application. The study concluded that ABATE is rapidly adsorbed by the sediment and is rapidly converted to ABATE sulfoxide.

Exhibit 5, *"ABATE® Residues in Salt Marsh Substrates,"*[5] was submitted to suggest that temephos is not persistent in saline environments. This study was conducted in 1973-74 as part of the proceedings of the Sixty-Third Annual Meeting of the New Jersey Mosquito Control Commission. This study was conducted as a field study to measure residues of Abate in salt marsh substrates. In 1973 a 1.5 acre plot near Tuckerton, New Jersey was treated at 2-week intervals with 10 granular applications of Abate 2CG as described above. In addition, in 1974 a 7.5 acre salt marsh plot near Manahawkin was treated with 4 liquid applications of Abate 4E at 0.032 lb ai/A at 2-week intervals. At the Tuckerton site water was monitored on an hourly basis for Abate residues in 5 potholes. The following year 3 of the 5 potholes were monitored. Three potholes were monitored at the Manahawkin site after the applications. Algae, grass, and soil samples were taken at same potholes on day 1 and weeks 1 and 2 after application. Samples were also collected at control plots where Abate was not detected (limit of detection not given).

The following observations were made:

1. Granular liquid applications result in very low subsurface water concentrations. Higher residue levels remained in the mini-marsh potholes presumably due to the accumulation of organic matter in the potholes. However, it is also possible that residue levels were higher because there were little or no effects from tidal dilution. Surface water samples also revealed residue level more than 4 times the level found in subsurface water.

2. Abate applied to the surface of the water is transferred to the surfaces of plants, algae, and other available materials within 24 hours.

3. The sparse grass, *S. alterniflora*, which was subjected to flooding twice a day, had greater soil exposer than *S. patens* which is a dense grass and not subjected to daily flooding

While this study did demonstrate that temephos formulations tended to adsorb or accumulate in organic matter relatively rapidly, conclusions about persistence cannot be made due to the effects of tidal flushing. Clearly more work is needed in the area of sediment toxicity.

Exhibits 6, *"A Summary of Studies of the Impact of Temephos and Chlorpyrifos on the Saltmarsh Environment,"*[6] and Exhibit 7, A Study of the Effects of Abate Applied for Mosquito Larvae Control on Non-Target Organisms in a Maryland Tidal Marsh"[7] were submitted to

conclude that there is little or no effect on non-target insect component of the saltmarsh treatment site. Exhibit 6 was conducted as a field study to determine the impact of temephos (Abate on a salt marsh ecosystem. In 1973, 4 one acre plots (2 treated and 2 control) near Tuckerton, New Jersey were marked out for the measurement of effects of temephos to bird species. Two additional plots (1 treatment and 1 control) were marked for grass productive, non-target organisms, and .residues studies. Ten granular applications of Abate 2CG were applied as described above. In addition, in 1974, five 7.5 acre salt marsh plots near Manahawkin were treated with 4 liquid applications of Abate 4E at 0.032 lb ai/A at 2-week intervals. Two of the five plots were used as controls, one for the Abate 4EC treatment, one for a Dursban (Chlorpyrifos) treatment, and one as a bird control plot. Although the details of the studies are not given, observations and measurements were said to be bade at frequent, periodic intervals before, during and after treatment.

This study showed that the granular formulation reduced the density of natural fiddler crab (*Uca spp.*) populations and that fiddler crab activity was impaired by sublethal doses of temephos. These sublethal effects led to a 30% decrease in crab larvae's population after a fourth application due to the increased inability of the larvae to escape predatory birds. At another site, 4 applications of Abate 4E formulation were at 0.031 lb ai/A at biweekly intervals. This study concluded that "no adverse effects on non-target insects, including grass-inhabiting species, aquatics and nocturnal flyers, have been detected." However, the study author does not described how he reached this conclusion, or what methods were used to measure the effects.

The Exhibit 7 study, was conducted in August 1977 on the saltmarshes at the Deal Island Wildlife Management Area on the eastern shore of Maryland. Two hundred and fifty acres were treated with Abate 4E at a rate of 0.048 lb ai/A. One control plot about 2 miles south of the treatment plot was not treated. There were no replicate controls or treatment plots. The four test species of non-target organisms indigenous to salt marshes selected included the eastern oyster (70 individuals), the blue crab (10 individuals), the grass shrimp (140 individuals) and the mallard duck (10 individuals). Observations were made for mortality prior to, 24 hours after application, and 48 hours after application. The results from this study demonstrated that only negligible mortality resulted from the 48-hour exposure period. While these results are favorable for a 48-hour exposure period, the study did not allow for the monitoring of these effects over a longer time period. In addition, the study did not account for repeated applications as allowed under the current label.

Exhibits 8, *"Effects of Abate 2G and Abate 4E Mosquito larvicides on Selected Non-Target Organisms Coexisting with Mosquito Larvae in Woodland depressions,"*[8] and Exhibit 9, *"The Residual Effects of Temephos (Abate 4E) on Non-Target Communities"*[9] were submitted to conclude that invertebrate populations are expected to quickly recover to pretreatment levels. Exhibit 8 executed some field tests on the granular Abate 2G and the flowable Abate 4E in 1975. Laboratory studies determined that cladocerans were the most susceptible invertebrates and tests of 2.5 lb Abate 2G per acre resulted in 100% cladoceran mortality in the course of a single day, and this mortality rate continued for two consecutive days when new populations were

introduced. At 5.0 lb per acre (the maximum application rate) 100% mortality was observed for 5 consecutive days. After the 5th day total mortality occurred within 3 days, and after the 7th day a mortality of 30% occurred in 3 days.

For the field tests, the granular Abate 2G was applied at a rate of 5 lb/A and the flowable, Abate 4E, was applied by hand sprayer at the rate of 1 oz (0.031 lb) ai/A. The non-target organisms used in this study were representatives of the cladocerans, copepoda, astrocytes, and damselfly. The breeding sites were observed daily and 10 dips of water were taken at each site and poured through a plankton net. Population estimates were determined and recorded for a period of 5 days before treatment and 10 days after the treatment. The pre-treatment dips were used as the controls to record the natural development of untreated populations. This resulted in a total mortality of all 4 species of mosquitos tested and varying mortalities among the non-target organisms (copeponds, astrocytes, and damselfly nymphs). However, all the populations returned to their original population levels after 48 hours of the spray. Although these results are encouraging, it must be pointed out that these observations were the result of one single application. It also appears that no data was collected on how long it would have taken the mosquito populations to reestablish their populations. The labels instruct the users to "repeat applications as necessary." EFED is aware that populations can recover after pesticide application, especially when they occupy only a few acres. However, when a pesticide is utilized over a large area at frequent intervals for many years, the population may not be able to recover.

Exhibit 9 field tested 3 manmade ponds to assess the impact of temephos (Abate 4E) on non-target organisms. The first pond was untreated and served as a control pond, while the second and third were treated at a rate of 2.5 lb ai/A on May 14, 1982. The first and the third pond contained about the same water volume, shape, surface area, and depth, while the second pond differed enough to have a direct effect on the thermal regimen of the ponds. Three samples of 5 liters were collected at predetermined transects at each pond, filtered, and fixed in a 5% formaldehyde solution. Beginning on May 4, 1982, the ponds were sampled 3 times prior to application, then at 3 or 4 day intervals for the 2 weeks after application, then on a weekly basis throughout the season. The ponds were also sampled 5 times the following summer. Physicochemical characteristics were also measured at each sampling time.

Residual activity in the treated ponds was measured by collecting samples twice daily from the 3 ponds from 24 hours after treatment to disappearance of response. Bioassays were then conducted with groups of 25 fourth instar mosquito larvae were exposed for 24 hours.

Pretreatment sampling showed well-established populations of Diptera larvae and macro zooplankton (copepoda, Cladocerans and astrocytes). Immediate population effects on all these non-target species were observed in the treated ponds, while populations gradually recovered during the 3 weeks after the application. All spring mosquito populations of *Aedes spp.* were effectively eliminated after treatment. In the control pond they were gradually replaced by the summer species *Culex spp.* and *Cabers spp.* The same changes occurred in the treated ponds, but in a more abrupt fashion. The residual activity of temephos in the two treated ponds was shown

to be statistically different. As a possible explanation it was suggested that the warmer conditions and the prevailing proportionally larger air-water interface, which increase volatilization and photolysis, could account for the differences in the residual activity between the 2 treated ponds.

It was concluded that this study demonstrated that temephos did not persist in the treated water and that effective control could be achieved with minimal short-term impact. However, it must be pointed out that these observations were the result of one single application. It also appears that other mosquito species populations made their debut in as little as 7 days despite the spray activity, and under normal circumstances a repeat spraying may be required for additional mosquito control. Since this experiment only considered a single application, the long-term effects to non-target organisms under multiple application conditions are not known.

Data Submitted by Lee County

The following studies were conducted by the Mote Marine Laboratory for the Lee County Mosquito Control District to address missing data requirements. These field studies do not satisfy the data requirements under CFR 40, Part 158. However, a few of the studies warrant consideration as supplemental laboratory data and may be used in a risk assessment. Complete details of these studies including the raw data and GLP certification need to be submitted and validated by EPA. Due to unavoidable time constraints, EFED was only able to complete a qualitative review. Contextual explanations of why these studies do not satisfy the data requirements are presented below. Additionally, we emphasize the merits of the studies for purposes of mitigation.

1. *"Impact Assessment of Mosquito Larvicides on Nontarget Organisms in Coastal Wetlands"*[10] was submitted to satisfy guideline 71-1(b) (Acute Avian Oral Quail or Duck/TEP), 72-3© (Estuarine/Marine Toxicity Shrimp), and 72-3(d) (Estuarine/Marine Toxicity Fish/TEP), 72-3(e) (Estuarine/Marine Toxicity Mollusk/TEP-G), and 72-3(f) (Estuarine/Marine Toxicity Shrimp/TEP-EC)(e). Since no acute toxicity endpoints were reached in this study for any of the organisms assessed, the data requirements are not fulfilled. The purpose of this study was to measure the impact of Abate (temephos) and Altosid (methoprene) applications on coastal shorebird populations and their prey under field conditions. Three aerial applications of Abate were made on 8/27/88, 9/10/88, and 10/28/99 at an average rate of 0.031 lb ai/A (the maximum label rate is 0.047 lb ai/A) to 3 sites plus 1 control site. Exact application dates or rates for Altosid was not reported. Only Table 3 of the report lists “Application # 1" as applied between 7/30 - 8/04/88 at the Master’s Landing site. It is not known if any other applications of Altosid were made or when. Crabs and mussels were collected from the St. Jude area of Lee County, Florida up to 24 hours after application. Larvicide residue field collections included residue monitoring on mangrove leaves, water pools, leaf littler/detritus, fiddler crabs, and mussels. Residues on mangrove leaves were determined by collecting 30 leaves from each site. Leaf litter/detritus were obtained by collecting a composite sample from each site. Residues in water were collected in a 1-L water sample at each site. Residues in mussels

and fiddler crabs were determined by collecting at least 12 individuals from each site. The limits of detection for residue samples was 0.01 μg/L.

Three sites were also chosen for bird study sites. An additional control site was located in the mangrove and salt marsh fringes of Charlotte Harbor. The method used to monitor birds was routinely visit predetermined points and recording bird species seen and/or heard for three 5-minute intervals. The primary purpose of these recordings were to provide insight into the within group variation between observational periods at each point.

This study made a number of conclusions about Abate applications including the following.

- No acute toxicity was observed in adult fiddler crabs
- Tidal water did not retain larvicides in detectable amount for greater than 24 hours
- Mussels did not accumulate Abate in detectable quantities
- Fiddler crabs retained Abate in concentrations similar to that found in leaf litter which indicated possible internal bioaccumulation or physical adsorption to the crab shell
- Abate residues found in leaf litter persisted up to 96 hours after application
- Sediment samples contained a small but consistent amount of Abate for up to 168 hours
- At least 13 species of listed birds were observed at or near the habitat typically sprayed
- In total, 115 bird species were documented during the study period
- Most wading birds make heavy use of the isolated ponds upland of the saltern habitat, as well as the salterns, when standing water is present.

2. *"Impact Assessment of Mosquito Larvicides on Nontarget Organisms in a Saltmarsh Community and on Selected Listed Species of Marsh and Shore Birds of the Southwest Florida Coast"*[11] was additionally submitted to satisfy EPA Guidelines 71-4(a) (Avian Reproductive, Quail), 71-4(b) (Avian Reproductive, Duck), 72-3(d) (Estuarine/Marine Toxicity Fish/TEP), 72-3(e) (Estuarine/Marine Toxicity Mollusk/TEP-G), and 72-3(f) (Estuarine/Marine Toxicity Shrimp/TEP-EC). This study was submitted as two separate studies.

   The objective of the first study was to assess the impact of temephos on larvae and juveniles of nontarget saltmarsh organisms during a 15-month period (July 1, 1989 to September 30, 1990). Five field applications were made with temephos (Abate 4-E) at the rate of 0.031 lb ai/A (the maximum label rate is 0.047 lb ai/A) on 7/21/89, 8/18/89, 9/14/89, 8/7/90, and 9/7/90. The primary organism of study was the larvae of the marsh fiddler crab (*Uca rapax*). However, the mangrove tree crab (*Aratus pisonii*) and the marsh crab (*Sesarma sp.*) were also tested as well as the snook fry (*Centropomus undecimalis*), the adult specimens of the invertebrate (*Mysidopsis bahia*), and the sheepshead minnow (*Cyprinodon variegatus*). In addition, two field sites were monitored on July 7 and September 6, 1990 as field controls without a temephos application to assess the survival of the marsh fiddler crab (*Uca rapax*), the mangrove tree crab (*Aratus pisonii*), and snook fry (*Centropomus undecimalis*) larvae. All were compared to the

mortality rate of the target saltmarsh mosquito larvae *Aedes taeniarhynchus*. To measure temephos distribution and persistence at the surface glass fiber filter pads were placed at ground level and collected one hour after application. Water samples were also taken before and after application to measure exposure to aquatic organisms. The amount of temephos remaining in the mangrove canopy was established by analysis of mangrove leaves at various time intervals after application.

The following conclusions were made by the study authors:

- Temephos residues in water after application ranged from 0.6 to 108 μg/L (limit of detection in water = 0.5 μg/L) . In the 1989 studies the third application showed about 2 ppb while the 1990 studies showed an average of 0.7 ppb after 24 hours.

- Small concentrations (limit of detection = 0.3 μg/g) of temephos were recovered from both the *Uca* and *Aratus* crabs as well as the coffee bean snail, ribbed mussel, and sheepshead minnow, indicating a potential for accumulation in the food chain.

- Temephos was observed to be almost 10 times more concentrated at the water's surface which indicated that organisms in contact with the water surface are more vulnerable.

- *Uca* larvae exhibited 50% mortality at the control site and an average of 35% mortality at the test sites in the 1989 studies. However, study author concluded that the mortalities observed were not treatment related effects.

- The 1990 studies concluded that there was a 30% mortality of *Uca* crabs and a 20% mortality of *Aratus* crabs 6 hours after application. However, the mosquito larvae experienced a 100% mortality. The studies authors conclude that there was no acute toxicity to these crabs under these field application conditions.

- The study authors also noted that there was a difficulty with the coordination of these studies because the crab larvae were not frequently present when mosquito larvae are developing. The authors believe that better timing of temephos applications could avoid exposure to crab larvae.

The second study was a follow-up of a previous avian one year study in which over 115 bird species were documented as having used the marsh study areas. Thirteen of these species were listed species. The objective of this study was to 1) determine what levels of temephos were in the eggs and/or young of selected species at various distances from the study area; and 2) determine where these birds were feeding. Key bird species and rookery sites were selected for the study in accordance with availability and abundance as well as their likelihood of representing the top level of the food web. (It was pointed out that a limited number of osprey and possibly great blue heron eggs were collected and

broader geographic coverage of colonies were limited because many of the key species occupied the centers of the colonies and were, therefore, unobservable.) Eggshell thicknesses for collected eggs were measured, and the only conclusion that could be made was that temephos could not be detected (detection limit not stated) in any of the 40 eggs or 8 prey items that were analyzed. A number of recommendations were proposed to up-grade this study.

Due to nature and design of this study as well as the deviation from the guideline protocols, this study can not be used to satisfy any parts of the avian reproductive guideline requirements.

3. *"Fate and Toxicity of Abate® Applied to an Estuarine Environment"*[12] was submitted to satisfy EPA Guidelines 72-3(a) (Estuarine/Marine Toxicity Fish), 72-3(d) (Estuarine/Marine Toxicity Fish/TEP), 72-3(e) (Estuarine/Marine Toxicity Mollusk/TEP-G), and 72-3(f) (Estuarine/Marine Toxicity Shrimp/TEP-EC), and 70-3 (Chronic Sediment Toxicity Tests for Freshwater and Estuarine/Marine Animals). This study was conducted as field study. Five applications of Abate® 4EC were applied in three separate episodes and monitored under field conditions with the objective of "determining the distribution and persistence of temephos applied to an estuarine environment during routine applications and to establish the acute toxicity to select marine organisms under normal larvicide application conditions." This test did not follow EPA guidelines for acute toxicity testing under laboratory conditions and did not obtain an LC50 as required. Further, the test species used to conduct this field study are not the species required by the guideline. The acute and chronic sediment toxicity testing requires the use of sediment-dwelling marine amphipod species for testing. These species are *Ampelisca abdita, Eohaustorius estuarius, Leptocheirus plumulosus, or Rhepoxynius abronius.* The six species tested in this field test were the mysid shrimp (*Mysidopsis bahia*, snook (*Centropomis undeimalis*), brown shrimp (*Panaeus aztecus*), grass shrimp (*Palaemonetes pugio*), sheepshead minnow (*Cyprinodon variegatus*), and pinfish (*Lagodon rhombiodes).* These species are endemic to shallow estuarine environments, but are not sediment dwelling organisms. Therefore, this study can not be substituted as an acute or chronic sediment toxicity guideline study. In addition, since temephos was applied to an uncontrolled site where temephos was allowed to dissipate to a large area within the estuarine environment, exposure to organisms was minimal. It appears that this minimal exposure did not allow toxicity endpoints to be established. The authors also indicate that "controlled tests to monitor the acute and sublethal effects should be undertaken."

Since no acute toxicity endpoints were reached in this study for any of the organisms assessed, the data requirements are not fulfilled. Despite the study's shortcomings of fulfilling the EPA sediment toxicity guidelines the study appears to provide some useful field information.

One control and one test area were studied. Three separate application episodes of

Abate® 4EC were monitored at a rate of 0.031 lb ai/A . The first episode was a 96-hour period where 2 applications were applied at 4 day interval (June 13 and June 17) with sample collections for residue analysis and toxicity monitoring of caged organisms at intervals of 1 hr, 6 hrs, 24 hrs, and 48 hrs after each application. The second episode was a 24-hour period where 1 application was applied on July 24 with sample collections and toxicity monitoring at 1 hr, 3 hrs, and 24 hrs after application. The final episode was a 96-hour period where 2 applications were applied at a 3-day interval (September 29 and October 2) with sample collection and toxicity monitoring at 1 hr, 2 hrs, 4 hrs, 7 hrs, 24 hrs, and 72 hrs after the first application, and 1 hr, 2 hrs, 4 hrs, 7 hrs, and 24 hrs after the second application. The objective of the study was "determining the distribution and persistence of temephos applied to an estuarine environment during routine applications and to establish the acute toxicity to select marine organisms under normal larvicide application conditions."

Residue data was collected on the surface water, mangrove leaves, sediment, and oysters. For field toxicity tests, 6 estuarine species were observed for behavior and mortality. These species are *Ampelisca abdita, Eohaustorius estuarius, Leptocheirus plumulosus, or Rhepoxynius abronius.* The six species tested in this field test were the mysid shrimp (*Mysidopsis bahia,* snook (*Centropomis undeimalis*), brown shrimp (*Panaeus aztecus*), grass shrimp (*Palaemonetes pugio*), sheepshead minnow (*Cyprinodon variegatus*), and pinfish (*Lagodon rhombiodes)*. The study authors conclude that "appreciable acute toxicities were not observed for the intertidal estuarine organisms studied, primarily because the daily tidal movement rapidly dispersed pesticide-containing water. Abate persistence was observed on mangrove leaves and in simulated tidal pools, indicating that potential toxicity problems could occur in static pools in the upper salt marsh areas."

4. *"Effects of the Mosquito Larvicide, Temephos, to Nontarget Organisms in a Saltmarsh Community"*[13] was submitted to satisfy EPA Guideline 72-4(b) (Life Cycle Aquatic Invertebrate), 72-3(d) (Estuarine/Marine Toxicity Fish/TEP), 72-3(e) (Estuarine/Marine Toxicity Mollusk/TEP-G), and 72-3(f) (Estuarine/Marine Toxicity Shrimp/TEP-EC). The goal of this study was to determine whether or not the use of temephos in a south Florida saltmarsh creates an unacceptable risk to nontarget organisms within the marsh. Field toxicity was determined as mortality (acute toxicity) to larvae of the *Aratus* and *Uca* crab species within 6 hours of field exposure and as percent mortality during the first molt (5 to 7 days exposure). However, the results of the field tests did not show effects under these conditions, and as a result laboratory toxicity tests were used to determine the acute toxicity of temephos to these crabs.

For the field studies a series of five applications at a of rate of 0.015 lb ai/A (the maximum label rate is 0.047 lb ai/A) on 6/5/92, 7/31/92, 8/28/92, 10/16/92 and 10/23/92. The laboratory toxicity tests were conducted for the *Aratus* crabs using both static and water exchanges systems on 4/21/92, 5/4/92, 5/19/92, and 6/9/92. The *Uca* crabs were tested

on 7/15/92, 9/4/92, and 9/29/92. These studies were said to follow EPA protocols, but complete details and the raw data of these studies did not appear in the report. Further, most of the *Uca* tests experienced more than 50% control mortality before the end of the 96 hour test. However, LC_{50}s for 48 hours were obtainable in most tests. 48 hour LC_{50}s ranged from 6.4 to 49.8μg/L for *Aratus*. *Uca* larvae were much less susceptible to temephos exposure and most tests exhibited control survival through 96 hours. *Uca* 96 hour LC_{50}s ranged from 5.6 to 14.9 μg/L. 48-hour LC_{50}s ranged from 56 to >67μg/L.

In addition, a 7-day chronic toxicity test was conducted according to EPA guidelines mysid shrimp (*Mysidopsis bahia*). However, very scanty details of the study were presented in this report, and raw data were not included. The four test concentrations run were 5, 10, 20, and 40 μg/L in eight replicates. The results indicated that the NOAEC for survival, fecundity, and growth was greater than the highest concentration tested (40μg/L). Since no effects were observed at the highest concentrations tested, an LOAEC was not obtained. Such a study, if submitted for review to EFED under GLP certification could only be accepted as supplemental at best if all other test criteria were met. A requirement of a new study to establish a LOAEC would depend on expected environmental concentrations generated from application rates, intervals, and frequencies.

The significant conclusions made from this study by the authors are:

- aerial applications made to saltmarsh at the rate of 1 fl. oz./A (0.031 lb ai/A) was suspected for causing adverse effects on *Aratus* and *Uca* crab larvae.

- the reduction of aerial application to 0.5 fl. oz./A (0.015 lb ai/A) reduced field concentrations below acute toxicity levels for *Aratus* larvae and below the no effects level for *Uca* larvae.

- Laboratory toxicity tests showed more toxicity to *Aratus* than *Uca*.

- *Aratus* larvae were only found in the lower marsh areas which were not being directly sprayed.

- duration of the exposure to crab larvae was generally less than 24 hours due to tidal flushing.

- A complete field study for long term effects on *Uca* is now needed.

5. *"Temephos Distribution and Toxicity in a South Florida Saltmarsh Community, November, 1993"*[14] was submitted to satisfy EPA Guideline 72-4(b) (Life Cycle Aquatic Invertebrate), 72-3(d) (Estuarine/Marine Toxicity Fish/TEP), 72-3(e) (Estuarine/Marine Toxicity Mollusk/TEP-G), and 72-3(f) (Estuarine/Marine Toxicity Shrimp/TEP-EC). The purpose of this study was to determine if aerial application of temephos is detrimental to

non-target organisms in a South Florida mangrove fringing saltmarsh community. The experimental approach was to assess the environmental exposure and follow-up with an evaluation of the environmental hazard to representative saltmarsh organisms based on laboratory toxicity tests. The final outcome was to propose application conditions which would reduce the risk to non-target organisms while providing effective control of mosquito larvae.

To assess the environmental exposure an aerial application of temephos was applied to upper and mid-marsh areas on September 2, 1993 where the most abundant crab species (*Uca rapax* and *Aratus pisonii*) were known to occur. The application rate was not specified in the actual body of the report, however, the summary indicated a rate of 0.5 fl. oz./A (0.015 lb ai/A). Water samples at the surface and mid-level depths were collected prior to and at 1 and 5 hours after application. The results showed that temephos concentration after 1 hour ranged from 3 to 10 μg/L at the low tide mid-marsh *Uca* site. The concentrations ranged from 1.0 to 1.8 μg/L temephos at high tide five hours after application. These concentrations were considered to be the expected environmental concentrations (EECs). None was detected at the lower marsh.

A second application was applied on September 17 to the upper marsh area only at low tide and water samples were collected prior to and at 1, 4, 5, and 6 hours after application. Samples were again collected at surface and mid-depth at the upper, middle, and lower marsh sites. The results showed that no temephos was detected in the middle or lower marshes during the out-going tide, and it was concluded that temephos was not transported in detectable amount from the upper marsh application area through the mid and lower marshes.

The environmental hazard evaluation was determined by comparing the EECs from the field studies to the Estimated Toxic Threshold (ETT) determined from both laboratory and field toxicity tests. The ETT was defined as the concentration of temephos exposure at which there was no difference in percent survival between test and control larvae through two days past the first molt. Laboratory toxicity tests for determination of the ETT were performed for both the *Uca* and *Aratus* crab larvae with both the technical form of the active ingredient and the product formulation (Abate®).

The larvae for the toxicity tests were used 1 to 2 days after enclosure, and to simulate tidal flushing the exposure water was exchanged at 70% at 6 hours, 50% at 24 hours and 50% every 48 hours thereafter. Three replicate sets of 20 larvae at 5 concentrations and 2 replicate sets of controls, one in saltmarsh water and one set in water plus methanol which was used as a dispersant. The test concentration levels for temephos were 2.5, 5, 10, 15, and 20 μg/L. For the Abate formulation the test concentrations were 2.5, 5, 7.5, and 10 μg/L, based on the amount of temephos in the water.

The results of tests for both the technical grade and the Abate formulation appeared to show no differences in toxicity with ETTs in the range of 5 μg/L. In all tests control mortality drastically increased after molting. If the 5 μg/L ETT is accepted, the EEC range of 3 to 10 μg/L exceeds the ETT by as much as about two fold. However, the EFED currently has valid test data on the pink shrimp that indicates an LC_{50} of 5.3 μg/L, which would make this commercial species even more sensitive (lower ETT) than the crab larvae species.

The objective of these tests was to establish effects on survival through the first molt. Field toxicity tests were also conducted in the salt marshes by exposing mosquito and crab larvae (*Aratus ppisonii*) for 6 hours (5 hours for the 1993 study), then removing them from the marshes. They were promptly returned to the laboratory and monitored for a period of 12 days. The tests run in 1992 utilized *Aratus* crab larvae and mosquito larvae. The 1993 tests run the *Uca* crab larvae and the saltwater mosquito larvae, *Aedes thaeniorhynchus*.

The results of the 1992 field tests concluded that there was no immediate concern about acute toxicity from the field exposure. However, a significant increases in mortalities (almost 50% in one test) observed through the first molt. The 1993 studies showed an increase in mortality during the first molt for *Uca* larvae in the mid-marsh, but no effect for *Aratus* larvae in the lower marsh. The environmental concentrations observed following the 9/2/93 application exceeded the ETT range of 5 μg/L, and thus, demonstrated an environmental hazard to crab larvae in the mid-marsh area.

The conclusion of this study is that when applications are restricted to the upper marsh areas strongly reduce or eliminate the risks to saltmarsh crab larvae. Effective control of mosquito larvae is also accomplished. Since the laboratory toxicity studies do not follow EPA guidelines or protocols with regard to the selection of test species, determination of LC_{50} , etc., these studies do not satisfy the guideline requirements. However, these may have some merit as supplemental studies that could be used in a risk assessment. To accomplish this, the details of these studies including the raw data and GLP certification would have to be submitted and validated by EPA.

6. *"Ecological Impact Assessment of Abate® on Florida State Lands/Saltmarsh Communities"*[15] was submitted to satisfy EPA Guideline 72-4(b) (Life Cycle Aquatic Invertebrate). The goal of this study was to address the concern for possible adverse effects from applications of the mosquito larvicide abate (temephos) on State-owned saltmarsh lands along the intertidal regions of Cape Coral, Florida. To account for the extreme environmental conditions due to the monthly variations from wet to dry it was decided that the most representative indicator organisms to monitor would be the benthic macroinfauna. Both control and application areas were designated for monitoring the benthic infauna and temephos concentrations before and after the applications.

Another component to the study was the application of adulticides (malathion or baytex) over residential areas as needed after adult mosquitoes emerged. Therefore, the drift from these adulticides was also monitored.

Temephos was aerially applied three times in 1995 (5/1, 5/22, and 6/6), 1996 (6/14, 7/3, and 7/20), and 1997 (5/14, 6/25, and 7/17) at a rate of 0.5 fl. oz./A (0.015 lb ai/A). For adequate replication of samples the number of test and control sites were increased from two to four pairs of sites for 1996 and 1997. Samples were collected at each site at the water (surface micro layer and mid-depth), surface sediment, and at glass-fiber filter pads to monitor the amount of larvicide deposition to the marsh surface. The monitoring included collections at pre-application, 2 hours, 24 hours, and 96 hours post-application for the 1995 applications. Filter pads were retrieved 1 hour post-application for 1996 and 1997. Invertebrate samples were collected pre-application and 96 hours post-application at each study site, and a Hester Dendy invertebrate settlement collector was added in 1996 and 1997 sampling to reduce the natural habitat variability from one site to another. Snail mesocosm studies were also established to assess the impact on natural populations of marsh invertebrates. One control site and one test site was used and monitored 96 hours after the 6/1/95 application and during final field collection on 10/11/95.

From data collected from the 1995 data analysis it was concluded that no temephos was detected at the surface water and very little in the mid-depth water after 96 hours. Sediment samples showed a small amount of temephos in surface water sediment with none after one hour and none detected after 24 hours (limits of detection = 0.1 μg/g). The percent recovery from spiked samples was somewhat low for sediment ranging from 60 to 69% for sediment. Concentrations on filter paper ranged from 336 to 176 $\mu g/m^2$ after one and two hours respectively and none detected after 24 hours (limit of detection = 0.01 $\mu g/m^2$. The 1995 snail mesocosm study showed no consistency from the control site to the test site.

Data from 1996 showed no detectable levels of temephos residue in sediment sample after any of the applications. Average concentrations in the water column ranged from 7.5μg/L after 1 hour to less than detectable levels after 24 hours.

From 1997 data it was concluded that due to no detectable temephos levels in the control areas, there was no drift from test site applications. Tests area concentrations show that most of the temephos was deposited on the filters and the surface water micro layer. Only 5 to 10% of the temephos found in the surface water micro layer was found mid-depth water samples after one hour. Both mid-depth and surface water concentrations diminished to less than detectable concentrations with the exception of mid-depth water at two sites during the first application. Again, temephos was not detected in surface sediment samples. The consistently low recovery of standard temephos from mid-depth could reflect temephos interaction with dissolved and particulate organic matter.

In the 1995 malathion application monitoring it was stated that the results show the potential for impact on the study areas, and that more extensive analysis of water samples within the study areas should be collected. The 1997 application showed drift into the study areas ranging from 27 to 8.5 $\mu g/m^2$ on filter paper. Concentrations of malathion in water was not measured and an extrapolation based on the ratio of temephos concentration on filter paper to mid-depth water concentration. Such a comparison is not valid.

Benthic macro invertebrate fauna for 1995 concluded that short-term temephos and malathion exposure was evident, but there was no evidence of long- term exposure or bioaccumulation. Fifty seven (57) invertebrate species were recovered from benthic core samples at all sites. Samples also showed that there was a high level of temporal and spatial variation in species numbers and abundance, and species diversity and equitability were noted to be greater at the control sites.

In 1996 a total of 14,456 individuals representing 88 benthic invertebrate taxa were recovered. The samples showed a high level of temporal and spatial variation. The taxa were strongly dominated by only 11 taxonomic groups and consisted mostly of insect groups, although oligochaetes and gastropods were also abundant.

Low abundance or the lack of occurrence of species in samples do not provide sufficient data for the conclusion of temephos effects. Of the common abundant taxa only Chironomidae showed a decrease in abundance for two of the three treatments, but there was some degree of uncertainty because of the variation of these taxa in the control plots, which also experienced declines in abundance after the second and third treatments.

Data collection methods for 1997 was similar to 1996, but field observations indicated that 1997 was a more “stressful” year with generally less water throughout the site and shorter periods of total inundation, although all sites were inundated during the testing periods. These observations were reflected in the overall declines in abundance and species. In 1997 only 5,206 individuals (36% of 1996) and 71 species (81% of 1996) were recovered. Abundance for core samples did not exhibit trends when post-application data were compared to control or pre-test plots. Only one of the dominant taxa, *Orchesta spp.* showed a consistent decline in numbers after each application. However, the controls responded in a contradicting fashion, showing a decline for the first application and increases for the second and third applications. When arthropods were targeted for ANOVA analysis, results showed no significant differences between pre- and post-application comparisons, station versus type, or station x type x study. However, it did indicate significant differences as well as interactions between dates and stations. It is concluded that in order for these results to have ecological meaning the applications must have the same effects regardless of the application dates. As an illustrative example, they cite that if mosquito larvae responded to temephos in the same manner as the arthropod fauna, it would be considered an ineffective larvacide. They also concluded that “the

faunal variability of the sites is related to the periodic nature of the inundation by tidewater or rainwater and subsequent drying".

Bibliography

1. Sanders, Herman O. and Walsh, David O., and Campbell. 1981.; Abate: Effects of the Organophosphate Insecticide on Bluegills and Invertebrates in Ponds. U.S. Fish and Wildlife Service. Technical Bulletin 104.

2. Siefert, et. al. 1986. Effects of Abate® (Temephos) on Non-Target Aquatic Organisms in a Natural Pond Undergoing Mosquito Control Treatment. U.S. EPA Environmental research Laboratory Progress Report, Duluth. 105 pp.

3. Residues of CL 52,160 [temephos] in Water and Mud from Streams and Ponds. American Cyanamid company, Report No. C-74, March 1965.

4. Abate®: Abate and Abate Sulfoxide Residues in Environmental Samples - Water, Sediment and Four Aquatic Species (Chrisfield, MD and Newark, DE). American Cyanamide Company, Report No. C-333, November, 1972.

5. Carey, W.E. and R. Iadevaia. 1976. Abate Residues in Salt Marsh substrates. Proceedings of the 63rd Annual Meeting of the NJ Mosquito Control Commission, pp. 186-193.

6. Forgash, A.J. 1976. A Summary of Studies of the Impact of Temephos and Chlorpyrifos on the Saltmaarsh Environment. Proceedings of the 63rd Annual Meetign of the NJ Mosquito Control Commission, pp. 94-98.

7. MD Department of Agriculture. A Study of the Effects of Abate, Applied for Mosquito Larvae Control on Non-Target Organisms in a Maryland Tidal Marsh. 1977. Unpublished Report. 9 pp.

8. Liem, K.K., and R.N. LaSalle. 1976. Effects of Abate 2G® and Abate 4E® Mosquito Larvicides on Selected Non-Target Organisms Coexisting with Mosquito Larvae in Woodland Depressions. Mosquito New 36(2): 202-203.

9. Fortin, C., A. Maire, and R. LeClair. 1987. The Residual Effect of Temephos (Abate® 4E) on Non-Target Communities. Journal of the American Mosquito Control Association. 3(2): 282-288.

10. Pierce, R.H., Henry, M.S., Proffitt, L.S., and Evans, R.K. 1989. Impact Assessment of Mosquito Larvicides on Non-Target Organisms in Costal Wetlands. Mote Marine Laboratory, Sarasota, Fl.

11. Pierce, R.H., Henry, M.S., Levi, M.R., and Lincer, J.L. 1990. Impact Assessment of Mosquito Larvicides on Nontarget Organisms in a Saltmarsh Community and on Selected Listed Species of Marsh and Shore Birds of the Southwest Florida Coast. Mote Marine Laboratory, Sarasota, Fl.

12. Pierce, R.H., Brown, R.C., Henry, M.S., Hardman, K.R., and Palmer, C.L.P. 1988. Fate and Toxicity of Abate® Applied to an Estuarine Environment. Mote Marine Laboratory, Sarasota, Fl.

13. Pierce, R.H. 1993. Effects of the Mosquito Larvicide, Temephos, to Nontarget Organisms in a Saltmarsh Community. Mote Marine Laboratory, Sarasota, Fl.

14. Pierce, R.H. 1993. Temephos Distribution and Toxicity in a South Florida Saltmarsh Community. Mote Marine Laboratory, Sarasota, Fl.

15. Pierce, R.H. Henry, M.S., and Culter, J.K. 1998. Ecological Impact Assessment of Abate® on Florida State Lands/Salt Marsh communities. Mote Marine Laboratory, Sarasota, Fl.